



Administrative Rules Review Committee

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THE RULES DIGEST

June, 2008

Scheduled for committee review
WEDNESDAY, June 11th, 2008
Senate Committee Room #116

Reference
XXX IAB No. 23 (05/07/08)
XXX IAB No. 24 (05/21/08)

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PUBLIC HEALTH DEPARTMENT

9:05

Smoking restrictions, SPECIAL REVIEW, EMERGENCY FILED.

2008 Iowa Acts, House File 2212 sets out specific restrictions on smoking; section 8 of the Act delegates both enforcement and rulemaking duties to the Department of Public Health.

In essence, the Act prohibits smoking in any enclosed space including places of employment or places of public use; exceptions include tobacco shops, private residences, personal motor vehicles, certain commercial motor vehicles, and the gaming area of a casino. The prohibition also applies to a variety of outdoor locations; these include:

- Outdoor sports and entertainment events;
Restaurant patios;
School grounds, including parking lots, athletic fields, playgrounds, tennis courts, and any other outdoor area under the control of a public or private educational facility including inside any vehicle located on such school grounds" [Note: the school grounds restriction is very broad and would appear to include the entire campus; there is nothing in the Act that indicates that the

term "school" is limited to K-12 schools or public schools];

- The grounds of public buildings, excluding the state fairgrounds, corrections institutions or parts of the Iowa National Guard.

The "grounds" restriction is a significant issue; the proposed rules define this term, adding needed detail and somewhat limiting the scope of the term:

"an outdoor area of a public building that is used in connection with the building, including but not limited to, a sidewalk immediately adjacent to the building; a sitting or standing area immediately adjacent to the building; a patio; a deck; a curtilage or courtyard; a swimming or wading pool; or a beach, or any other outdoor area as designated by the person having custody or control of the public building."

The rule provides that the person in charge of a public building may exclude from the designated grounds of any public building a parking lot, the course of play at a golf course, a hiking trail, locations of an individual campsite or campfire, or a lake, river, or other body of water. At the same time, the person in charge of a public building can prohibit smoking in any area, even if that area would be exempt under the statute.

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The Department is required to provide notice of the provisions of the Act to all applicants for a business license, all law enforcement agencies, and to any business required to be registered with the Secretary of State.

The owner or operator of any location restricted under the Act must post no smoking signs, and must warn patrons who are violating the restrictions. The rules establish a hierarchy of actions in dealing with persons improperly smoking. If the person refuses to stop smoking, the owner or operator "should" discontinue service to that person and "may" request that the person leave the area. If the person refuses to leave the area the owner or operator may notify law enforcement. Note that the terms "should" and "may" are not mandatory, thus none of these actions beyond a warning are mandatory. As with public buildings, the owner or operator may designate areas as non-smoking even if exempted under the Act.

The Act has extensive enforcement provisions. The Department of Public Health is required to adopt rules to administer these provisions, including rules regarding enforcement. Hotel, food service, building or any other type of government inspector is required to assess compliance with these requirements and report any violations to the Department. An employee or private citizen may bring a legal action to enforce the restrictions or may file a complaint with the Department.

The Department or any other person aggrieved or adversely affected by a violation of these restrictions may seek injunctive relief in the courts. Violations are designated a public nuisance and the Department may seek a restraining order, injunction, or take other legal action to abate the nuisance, including action to recover the costs of the abatement. Under the rules the Department has delegated authority to local law enforcement agencies to enforce these provisions.

Unlawful smoking carries a \$50 civil penalty; owners or operators of a restricted location that allows smoking are subject to a progressive monetary penalty and may be subject to the suspension or revocation of any permit or license issued for the premises:

- For a first violation, a penalty not to exceed one \$100;

- For a second violation within one year, a penalty not to exceed \$200;
- For each violation in excess of a second violation within one year, a penalty not to exceed \$500 for each additional violation.

An employer who discharges or discriminates against an employee who has sought to enforce the restrictions is subject to a civil penalty of not less than \$2,000 and not more than \$10,000 for each violation.

* * *

Oral health unit, IAB Vol. XXX, No. 24, ARC 6795B, NOTICE.

In 2007 Iowa Acts, Chapter 159 the position of state public health dental director was established and an oral health bureau was established, to promote dental health. The new unit will administer a variety of federal, state, and local initiatives, including Title V maternal and child health, including the Medicaid and EPSDT programs; I-Smile program; dental sealant program; fluoride mouth rinse program; dental care for persons with disabilities program; and senior smiles program.

* * *

Dental screening program, IAB Vol. XXX, No. 24, ARC 6798B, NOTICE.

2007 Iowa Acts, chapter 146 requires the parent or guardian of an elementary school child to provide evidence that between the ages of three and six the child has received a dental screening performed by a physician, a nurse, a physician assistant, a dental hygienist, or dentist. Similarly, the parent or guardian of a high school student must provide evidence that the student has received a dental screening performed within the prior year by a licensed dental hygienist or dentist. A school district or accredited nonpublic school is required to provide access to a process to complete the required screenings. The Act provides an exclusion for persons who are "unduly burdened" by the requirement (which is defined in rule as a financial hardship) or have a sincere religious conviction.

Under these proposed rules a dental screening is defined as a visual assessment that is noninvasive and nondiagnostic; it does not require the use of dental instruments. The screening can identify obvious or suspected oral health conditions that

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require or that might require examination by a dentist. It includes the following steps:

- Visual inspection of the soft tissues, including the lips, cheeks, gums, tongue, floor of mouth, and roof of mouth, to assess infection or injury.
- Visual inspection of all tooth surfaces to assess tooth decay or injury.
- Documentation of the screening and treatment needs.

The rules also provide that it is the *duty* of an elementary school or a high school to ensure that a valid certificate of dental screening or an exemption is on file for each child enrolled. The schools must also ensure that the parent or guardian of a student enrolled in the school has complied with the dental screening requirement.

As part of this program the department will maintain a statewide dental screening database to ensure that students receive the screening and to monitor oral health. The database will consist of information from the certificates of dental screening and exemption, along with identifying and demographic data. Information in the database is confidential and will be released only in limited circumstances, as outlined in the rule.

* * *

Lead blood testing, IAB Vol. XXX, No. 24, ARC 6801B, NOTICE.

Iowa Code Supplement §135.105D and 2008 Iowa Acts, Senate File 2111 require that every child enrolled in any elementary school must be tested for elevated blood lead levels or receive a waiver. The Department may grant a waiver if it determines that a child is of very low risk for elevated blood lead levels, or if the blood lead testing conflicts with a "genuine and sincere" religious belief.

Schools are required to give notice of the blood lead test requirement to parents at least ninety days before the start of the school year. Schools are also required, in collaboration with the Department, to assure that each student complies with the blood lead testing requirement. The Department is required to provide for testing for those children under six years of age who do not have insurance.

* * *

Preparedness advisory committee, IAB Vol. XXX, No. 24, ARC 6802B, NOTICE.

The Department proposes to create a preparedness advisory committee (PAC) to assist in the development of a public health emergency preparedness program for the department. This committee will consist of some 32 members, with "contributions and representation" from seven state agencies. Membership on the PAC is for three year terms and is drawn from a variety of health-related and professional organizations. Members do not receive a per diem but do receive actual expenses.

CORRECTIONS DEPARTMENT

9:50

Jail facilities, IAB XXX No. 24, ARC 6800B, ADOPTED.

These rules amend and update existing Department of Corrections practices for jail inspections and jail operations, and make minor changes to various definitions in chapter 50 of the Department's rules. They also specify certain requirements for jail facilities which are constructed or significantly remodeled after January 1, 2008. According to the proposed rules, exercise areas, following January 1, 2008, are required to have a minimum ceiling height of 18 feet.

The rules specify the procedure to inventory property taken from prisoners upon entering the jail and add bomb threats to the list of situations for which a jail administrator is required to have a written security plan.

Under this revision, continuous observation of a prisoner restrained in a four/five-point position by staff may be conducted in part by closed circuit television (CCTV). However, personal visual observation must be made at least every 15 minutes. The rules also specify that a jail's written suicide prevention plan must include annual training to recognize the potential for suicide. The jail's admission plan and procedure must include a mental health screening process and the jail is required to document all medication coming into the jail and the amount returned when a prisoner is released.

Finally, the rules remove a provision that requires the removal of a disciplinary report from the prisoner's file if the prisoner is found not guilty of violating the jail's rules.

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ELDER AFFAIRS DEPARTMENT

10:10

Resident advocate committees, IAB Vol. XXX, No. 23, ARC 6789B, NOTICE.

The Department proposes a re-write of existing provisions relating to the organization and operation of resident advocate committees. Iowa Code §135C.25 requires that each health care facility have a resident advocate committee, by the director of the Department of Elder Affairs.

Committee members must be a resident of the service area where the facility is located. Members cannot be an employee, consultant or administrator of the facility. In facilities serving 15 residents or less the minimum committee membership is one, in larger facilities the minimum membership is two. A committee must meet at least quarterly.

The committee represents and advocates for the rights of residents of the facility. Committee members investigate complaints and grievances. Under the proposal, the committee should:

"[s]eek to resolve the complaint or grievance and, if feasible, prevent unnecessary regulatory action against a facility. However, the committee shall not prevent or dissuade regulatory action when necessary to protect or achieve the rights of residents."

ENVIRONMENTAL PROTECTION COMMISSION

10:30

Stream designations, IAB Vol. XXX, No. 23, ARC 6351B, ADOPTED.

The federal Clean Water Act (CWA) established a goal that perennial streams (year-around flow) and pools be "fishable/swimmable." Every state is required to have water quality standards which meet this federal requirement and are approved by the federal Environmental Protection Agency (EPA). To implement this requirement, early in 2006 the EPC promulgated rules which designate some 26,000 perennial streams, and intermittent streams with perennial pools as Class A1, B(WW-1) protected waters; this is the highest designation, protecting the stream for recreational and aquatic life uses.

This rulemaking was later supplemented by legislation; 2006 Iowa Acts, Senate File 2363, to address the state's water quality standards. Under

the Act, the EPC is required to designate stream segments pursuant to designated uses, e.g., agriculture, aquatic, or recreational use.

As required in both the rules and the legislation, the EPC has begun a series of rulemaking proceedings to establish a specific designation for each Iowa stream, which is determined after a field study is conducted using specific criteria. In this process each stream is evaluated and assigned to one of three categories based on its condition. Primary contact recreational use (class A1) includes waters used for such things as swimming, diving, water skiing, and water contact recreational canoeing. Secondary contact recreational use (class A2) includes waters in which recreational or other uses, such as boating, may result in contact with the water that is either incidental or accidental. Children's recreational use (Class A3) includes waters in which recreational uses by children are common. Streams currently having an A1 classification may be downgraded if the study determines that the class A1 use is neither existing nor attainable.

That designation process has now begun; following six public hearings hundreds of streams are being re-designated. As specific designations are established, effluents from treatment facilities must be reduced to meet the assigned level. This will result in reduced levels of ammonia and bacteria. The 20-year cost to achieve this reduction is estimated to be as high as \$1 billion. However, those costs may be reduced for those streams with lower levels of protection.

PUBLIC SAFETY DEPARTMENT

10:40

On-site surveillance, IAB Vol. XXX, No. 17, ARC 6591B, ADOPTED---70 day delay from April 1.

Iowa law requires that gambling activities on excursion gambling boats be continuously recorded and Department rules implementing that requirement mandate the use of a closed circuit surveillance system.

The Department's rules provide that by 2011 all facilities must have digital recording systems and a closed network with limited access located on the same premises as the casino or on adjacent property. All equipment used to monitor or record views obtained by a surveillance system must also

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be located in a room on the same premises as the casino or adjacent property, and be used exclusively for casino surveillance security purposes. Policies must be in place relating to employee access levels and the transmission or release of live or recorded images, video, or audio.

At the committees March 2008 meeting representatives of the gaming industry contended that the degree of control that the Department exercises over the surveillance systems is neither necessary or effective; and they opposed the degree of control the Department will exercise over the surveillance system. They also questioned whether the Department properly has regulatory authority over the entire casino structure, contending that the authority applies to the actual gaming areas. In response to these concerns the committee imposed a 70 day delay on this filing, along with the request that the Department and the industry resolve these issues, with further review at the June meeting.

INSURANCE DIVISION

11:00

Pharmacy benefit managers, IAB Vol. XXX, No. 23, ARC 6781B, NOTICE.

These provisions implement 2007 Iowa Acts, Senate File 512. Proposed rules were initially published in January; following public comment that proposal was terminated and this new rulemaking commenced.

Senate File 512 regulates pharmacy benefits managers; these individuals administer or manage prescription drug benefits provided by a insurer, health benefit plan, health maintenance organization, or similar third-party payor program. Managers coordinate the policy benefit between the insured, the pharmacy provider network, and the insurer.

The proposed rules address recordkeeping, auditing procedures, complaint procedures, and conditions of terminating a pharmacy agreement. Section three of the Act specifically requires rulemaking for timely payment of pharmacy claims and for a process for adjudication of complaints and disputes.

Under the proposal a "clean claim" (i.e.: a claim that requires no further information):

"shall be paid as soon as feasible but within 20 days after receipt of a clean claim when the claim is submitted electronically and shall be paid within 30 days after receipt of a clean claim when the claim is submitted in paper format."

If the claim is not timely paid, the manager must pay the pharmacy or pharmacist interest at the annual rate of ten percent annum.

The pharmacy benefits manager must develop a complaint process; all complaints and the ultimate resolution must be submitted to the Division on a quarterly basis.

The rules contain detailed provisions relating to the auditing of the pharmacy network. The pharmacy benefits manager may audit a pharmacist, providing one weeks notice. A pharmacist must be consulted when the audit involves professional or clinical judgment. An audit period may not exceed two years.

A preliminary audit report must be delivered to the pharmacy within 120 days after conclusion of the audit. A pharmacy must be allowed at least 30 days following receipt of the preliminary audit report in which to produce documentation to address any discrepancy found during an audit. A final written audit report shall be received by the pharmacy within six months of the preliminary audit report or final appeal, whichever is later.

An audit appeal process must be provided, followed by an opportunity for external review by the Insurance Division.

A pharmacy agreement cannot be terminated solely because of filing a complaint, grievance or appeal, or because of any dispute relating to a decision of the pharmacy benefits manager to deny or limit benefits to covered persons, or any assistance provided to covered persons by the pharmacy or pharmacist in obtaining reconsideration of the decision. Prior to any termination the manager must provide written explanation to the pharmacy or pharmacist of the reason for the termination at least 30 days prior to the termination date unless the termination is based on the loss of the pharmacist or pharmacy's license to practice, cancellation of professional liability coverage or conviction of fraud. Termination is subject to review by the Division.

SECRETARY OF STATE

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11:15

HAVA Plan 2008, IAB Vol. XXX, No. 24, ARC 6791B, NOTICE.

In 2008 Iowa Acts, Senate File 2347 the legislature mandated for elections held on or after November 4, 2008, that a county use only an optical scan voting system. The Act also established an optical scan voting system fund under the control of the secretary of state, to be for purchase and distribution of optical scan voting system equipment to counties. In effect the Act prohibits the further use of direct-recording electronic voting machines (DRE). These devices record votes by means of an on screen ballot display that records data in memory storage. The use of DRE machines has been controversial, based on claims that the lack of a paper audit trail and the possibility of tampering could lead to voter fraud. Nineteen counties have all DRE systems while 59 more have a blended system.

These rules update the state plan for federal Help America Vote Act (HAVA) funding. The available funds will be used to replace DRE voting equipment or DRE blended systems in 78 Iowa counties.

PHARMACY BOARD

11:45

Pharmacy technicians and centralized prescriptions, IAB XXX No. 20, ARC 6668B and 6671B, ADOPTED, 70 day delay.

As provided in 2007 Iowa Acts, Chapter 20, starting July 1, 2010 all applicants for a new pharmacy technician registration or technician renewal must provide proof of current certification by a national certification organization. ARC 6668B relates to the organization of these registration requirements and detailed the role of registered technicians and the limitations on their function. A second rulemaking, ARC 6671B, relates to the operation of central fill pharmacies.

These filings were reviewed at the committees' April 2008 meeting; representatives of the pharmacy industry expressed concern with both filings. The Committee imposed a 70 day delay with the request that the board meeting with concerned stakeholders and attempt to resolve their concerns.

HUMAN SERVICES DEPARTMENT

1:00

PACE program, IAB Vol. XXX, No. 24, ARC 6806B, NOTICE.

The Department proposes to add Medicaid coverage for a new type of managed health care, "Programs of All-Inclusive Care for the Elderly" (PACE). The service provider is paid a prospective monthly capitation payment for each Medicaid enrollee. The monthly capitation payment amount is negotiated annually between the service provider and the Department, but must be less than the amount that would otherwise have been paid under the Medicaid program and is a fixed amount regardless of changes in the enrollee's health status.

Enrollment is limited to Medicaid recipients who are 55 years of age or older and who need care at the nursing facility level but are able to live in a community setting, receiving preventive and coordinated medical care that allows them to live in their homes. If a person chooses to enroll in a PACE program, the member must receive Medicaid benefits solely through the PACE organization while enrolled in the program.

Program services are determined by a comprehensive plan of care developed by an interdisciplinary team based on a comprehensive assessment of the individual. The interdisciplinary team provides an initial assessment, periodic reassessments, plan of care, and coordination of 24-hour care delivery for each PACE enrollee. An in person re-assessment must be conducted at least twice a year.

VETERINARY MEDICINE BOARD

1:40

General update--veterinary assistants, IAB XXX No. 22, ARC 6749B, NOTICE-HELD OVER FROM MAY.

This proposal contains a variety of amendments to the veterinary medicine board rules; many of the rules are "boilerplate" language relating to disciplinary hearings. The more significant changes add detail to the requirements of veterinary practice while others expand and re-define the role of veterinary assistants. This notice of intended action is the culmination of a multi-year review process.

New rules set out requirements for veterinary facilities generally relating to storage, equipment,

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sanitation, boarding, and lighting. The rules also detail the scope of veterinary practice activities, setting out a list of veterinary functions that include several new concepts: dentistry, pregnancy diagnosis, animal chiropractic, animal physical therapy, and veterinary acupuncture or acupressure.

Section 169.20 provides that a veterinarian may employ "certified" assistants working under the direct supervision of a licensed veterinarian. The Code does not detail the role of the assistants, but it does state that assistants may not provide diagnosis, prescription, or surgery.

Under the proposed rules, there are two types of assistants: veterinary technicians and veterinary assistants. Technicians are *licensed* and have completed a two or four year course of study and passed a veterinary technician examination. Assistants are *certified* after taking an examination. This proposal outlines the tasks that a technician or a certified assistant may perform under the direct supervision of a veterinarian and those the technician may perform under indirect supervision. There are three levels of supervision:

- "Immediate supervision" means that a licensed veterinarian is on the premises and within eyesight or hearing range.
- "Direct supervision" means that a licensed veterinarian is on the premises and is readily available.
- "Indirect supervision" means that a licensed veterinarian is not necessarily on the premises but is able to perform the duties of a licensed veterinarian by maintaining direct communication.

The rules contain an emergency exception allowing a licensed technician to perform certain life-saving functions in the absence of the veterinarian.

Both technicians and assistants must obtain periodic continuing education: technicians must obtain 30 credit hours in three years and assistants must obtain 15 hours.

These proposals relating to assistants have proven to be controversial. Public comment indicates there are less than 250 certified technicians in Iowa, and that as a matter of practicality unlicensed personnel must be used to provide patient care. The concerns can be best summed up in this quote from the Louisa Veterinary Clinic: "The ability to delegate routine

technical procedures will be compromised due to the lack of certified licensed veterinary technicians."

Concerns were also expressed over the requirement that a veterinary office maintain a separate surgical room. Comments indicated this could require extensive re-modeling or even relocation, without significantly improving the quality of care.

PROFESSIONAL LICENSURE DIVISION

No Rep.

Chiropractic assistants, IAB Vol. XXX, No. 23, ARC 6779B, NOTICE.

The board proposes rules relating to the duties of chiropractic assistants and the responsibilities of the supervising chiropractic physician. The new rules will take effect July 1, 2009.

A chiropractic assistant must complete a chiropractic assistant training program and under these rules may perform certain chiropractic health care services under the supervision of a chiropractic physician. The chiropractic physician may not delegate the following:

- Services outside the chiropractic physician's scope of practice;
- Initiation, alteration, or termination of chiropractic treatment programs;
- Chiropractic manipulation and adjustments;
- Diagnosis of a condition.

There are two types of chiropractic physiotherapy performed by a chiropractic assistant. "Active" chiropractic physiotherapy is performed by the *patient* with the assistance and guidance of the chiropractic assistant. "Passive" physiotherapy is performed by the assistant and received by the patient including, but not limited to, mechanical, electrical, thermal, or manual methods. The assistant must receive 12 hours of instruction, of which 6 hours shall be clinical experience for each type of physiotherapy performed by the assistant.